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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,012	08/28/2003	Raymond J. Tesi	A-71619/TAL/DSS	2107

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/653,012	TESI ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-19 *are pending*

2. It is noted that claim 8 recites "a method for inducing immune tolerance to *an antigen* in a recipient host, comprising...", which given its broadest reasonable interpretation consistent with the instant specification and claims, reads on inducing immune tolerance to either a *donor* antigen OR a *host* antigen in a recipient host (see, for example, claims 15 and 16).

   However, with respect to "inducing immune tolerance to a ***host*** antigen in a ***recipient*** host", it is unclear exactly ***what, if anything,*** the "***recipient*** host" is receiving.

   It is further noted that claim 8 recites "administration of an immunosuppressant taper". From the disclosure of the instant specification at page 7, 3rd paragraph to page 8, 1st paragraph, it is apparent that one does not "administer an immunosuppressant taper", rather one ***performs*** an immunosuppressant taper by ***administering an "immunosuppressant agent" which is tapered***. This is not clear from the recitation of claim 8.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

   I. Claims 1-7 and 16, drawn to a method of prolonging survival of a **donor** allograft/antigen in a recipient comprising administering **(1)** a lymphocyte depleter, **(2)** a deoxyspergualin compound and **(3)** an mTOR inhibitor/immunosuppressant taper, classified in Class 424, subclass 173.1.

   II. Claim 15 drawn to a method of prolonging survival of a **host** antigen in a recipient comprising administering **(1)** a lymphocyte depleter, **(2)** a deoxyspergualin compound and **(3)** an immunosuppressant taper, classified in Class 424, subclass 278.1.

   III. Claim 17, drawn to a method of prolonging survival of a **donor** allograft/antigen in a recipient comprising administering **(1)** a lymphocyte depleter, **(2)** a deoxyspergualin compound and **(3)** an mTOR inhibitor/immunosuppressant taper **AND further comprising administration to said host donor hematopoietic cells to induce hematopoietic chimerism**, classified in Class 424, subclass 93.7.

   IV. Claim 18 drawn to a method of treating **graft versus host disease** in a recipient comprising administering **(1)** a lymphocyte depleter, **(2)** a deoxyspergualin compound and **(3)** an mTOR inhibitor, classified in Class 424, subclass 183.1.

   V. Claim 19 drawn to **a kit** for use in the treatment of a transplant recipient comprising comprising **(1)** a lymphocyte depleter, **(2)** a deoxyspergualin compound and **(3)** an mTOR inhibitor, classified in Class 435, subclass 810.

4. Claim 8-14 link Groups I-III. The restriction requirement between Groups I-III is subject to the nonallowance of linking claims 8-14.

   Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

   Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Groups I/III, II and IV are different methods in that they read on **mutually exclusive patient populations**. For example, as disclosed in the instant specification at page 1, 3rd paragraph, the methods of Groups I/III read on prolonging survival of ***non-lymphoid donor allografts*** in a recipient, such as a kidney, whereas the method of Group IV recites "treating graft versus host disease" which, as disclosed in the instant specification, involves "transplants of ***donor lymphoid cells and tissue***" and "is caused by circulating donor T cells within the host which are ***acquired in bone marrow grafts***".

   Furthermore, the method of Group II differs from the methods of the other groups in that "prolonging survival of a **host** antigen in a recipient", reads on prolonging survival of host antigens involved, for example, in autoimmune diseases, such as diabetes (see instant specification, page 5, 3rd paragraph).

   In addition, the methods of Groups I and III differ from one another in one or more ingredients, method steps, and/or endpoints; therefore, these methods are patentably distinct, one from the other.

   Further, since the methods of Groups I-IV involve distinct patient populations or distinct ingredients, method steps, and/or endpoints they would require separate and distinct searches. As such, it would be burdensome to search these inventions together.

6. Group V and Groups I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, survival of a transplant allograft or tolerance to an antigen can be achieved with a materially different product, such as a non-steroidal anti-inflammatory or with a molecule that blocks T cell costimulation, such as anti-CTLA4.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. This application contain claims directed to the following patentably distinct species of the claimed invention:

9. If applicant elects **Group I or III,** applicant is **required to elect one specific allograft/antigen** for which survival will be prolonged or tolerance will be induced from among the allografts/antigens disclosed in the instant specification at page 1, 1st to 3rd paragraphs and pages 11-12, for example, **"kidney" OR "bone marrow"**.

   These **allograft/antigens** are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

   If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

   Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

10. Furthermore, if applicant elects any one of **Groups I-V**, applicant is **further required to elect** one **specific lymphocyte depleter**, for example, from among those recited on pages 5-6 of the instant specification, such as **"thymoglobulin™" OR "anti-CD52 antibody" OR "anti-CD3 antibody"**.

These **lymphocyte depleters** are antibodies which recognize antigens that are patentably distinct in that they have different structures, and/or physiochemical properties, and/or do not share a common structure that is disclosed to be essential for common utility. Thus, each lymphocyte depleter antibody binds a patentably distinct polypeptide, and in turn each lymphocyte depleter antibody has a unique structure and is *per se*, patentably distinct. Thus, searching these species would impose an undue burden. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

11. Furthermore, if applicant elects any one of **Groups I-V**, applicant is **further required to elect** one **specific deoxyspergualin compound**, for example, from among those recited on in claim 6, such as "**15-deoxyspergualin" OR "LF15-0195" OR "methyldeoxyspergualin"**.

These **deoxyspergualin compounds** are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

12. Furthermore, if applicant elects any one of **Groups I-V**, applicant is **further required to elect** one **specific mTOR inhibitor/immunosuppressant tapering agent**, for example, from among those disclosed in the instant specification at page 8, 1st-3rd paragraphs, such as, **"CsA" OR "rapamycin" OR "the rapamycin derivative everolimus" OR "the rapamycin ester CCI-779"**.

These **mTOR inhibitor/immunosuppressant tapering agents** are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

    Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

    Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

    In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

    If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

    Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
August 16, 2006.

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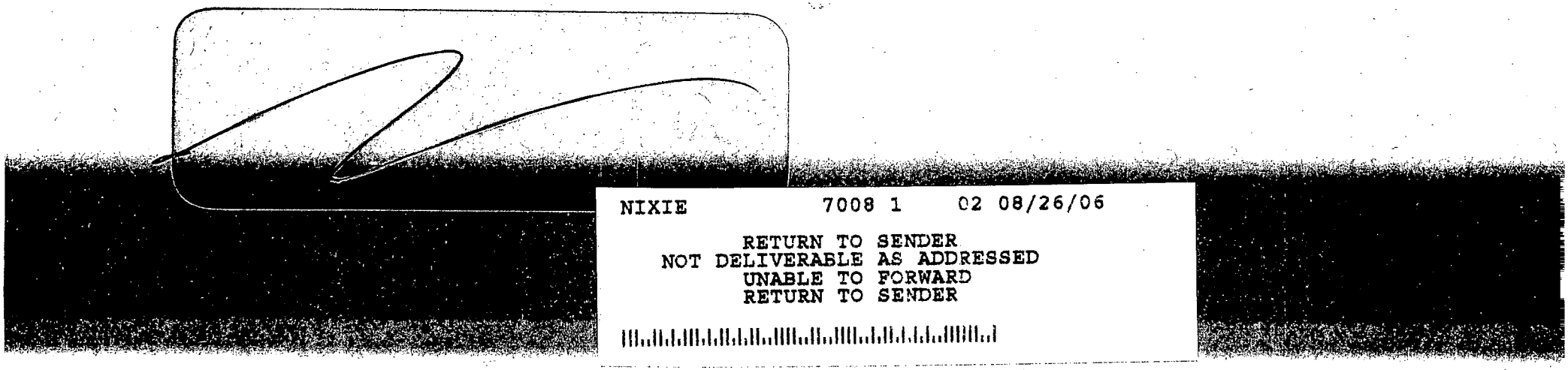

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